REMARKS

Rejections

All pending claims were again rejected under 35 U.S.C. 112, first paragraph, for allegedly containing subject matter not sufficiently described in the application- for use of the term "hollow".

Claim 17 was again rejected under 35 U.S.C. 112, second paragraph, for use of the term "molecule".

The Examiner has dropped the rejection of the claims under 35 U.S.C. 102(b) as being anticipated by WO 97/49387 ("Wooley").

Claims 1, 10, 12, 17, and 19 were again rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,008,184 ("Pluyter").

Claims 1, 10, 12, 17, and 19 were again rejected under 35 U.S.C. 102(a) as being anticipated by U.S. 5,891,468 ("Martin").

Claims 1, 3-6, 9-14, 16-20, and 27-30 were rejected again under 35 U.S.C. 103(a) as being obvious over WO 97/49387 Wooley by itself or in combination with Martin.

The Claimed Invention

The claimed invention includes vesicles made from triblock amphiphilic ABA copolymers, where one of A or B is hydrophilic and the other is hydrophobic, which self-assemble when dispersed in oil or water. The vesicles are hollow. Vesicles are defined on page 4 as "spontaneously forming aggregates having a generally spherical shape and an interior void." The resulting vesicles will have hydrophobic and hydrophilic layers arranged depending on the type of copolymer used.

The claimed invention further includes nanocapsules formed by stabilizing the vesicles made from ABA copolymers. The nanocapsules are also hollow. Stabilization can be through crosslinking of the copolymers, such as crosslinking of end groups of the copolymers.

The claimed invention further includes nanocapsules formed by end-group stabilization of amphiphilic copolymers. The copolymers do not have to be triblock copolymers.

Active agents can be encapsulated within the vesicles and the nanocapsules and targeting molecules can b attached to the vesicles and nanocapsules.

Analysis

112 Rejections

The term "hollow"

This rejection is again traversed. The term "vesicle" is clearly defined in the specification on page 4 as "spontaneously forming aggregates having a generally spherical shape and an interior void." An interior void means that the vesicle is hollow. The term "hollow" is defined on the online Merriam Webster dictionary (see Exhibit A) as "having a cavity within", such as a "hollow tree". Even though the interior of the tree is filled with air, it is still considered to be hollow. The vesicles of the invention do not have polymer in the interior, thus they have an interior void, i.e. they are hollow (see Exhibit B for the definition of the term "void" from the online Merriam Webster dictionary). They most likely are filled with fluid if they are in a liquid environment but they are still "hollow" as that term is commonly used. Although the term "vesicle" as used in the claims is clearly described in the specification as being hollow, the specific term "hollow" was added to the claims in an effort to more clearly illustrate to the Examiner the nature of the vesicles. The term is redundant, and Applicant is willing to delete the term from the claims, if that would obviate the rejection of the claims on this grounds.

The term "molecule"

The Examiner maintains the rejection of claim 17 as indefinite due to use of the term "molecule". Claim 17 is directed to incorporation of a molecule into the vesicle membrane. This rejection is again traversed.

As supported by Exhibit C, the common definition of the term molecule is that it is the smallest particle of a compound (or protein, for example) that has the chemical properties of that compound. In fact, "one specific membrane protein" is not made of several molecules as stated by the Examiner. One membrane protein is a single molecule. This use of the term "molecule" is supported in depth in the specification on pages 19-21.

102 Rejections

Pluyter

The rejection of the claims over Pluyter is again traversed. The present claims are drawn to vesicles and nanocapsules comprising membranes that are formed from amphiphilic copolymers. Pluyter teaches lamellar vesicles which may have copolymers "partially

incorporated" therein (col. 5, lines 51-55). The copolymers may be attached to the vesicles or incorporated within the vesicles but they do not form the vesicle. In fact, the polymers make up only 0.1 - 10%, most preferably only 0.5 - 2% of the compositions (col. 3, lines 57-59).

Applicants do not need to limit their claims to state that the membranes are "totally made from the copolymers" as suggested by the Examiner. It is clear that the claimed invention differs substantially from the cited art in that the membranes are "formed from amphiphilic copolymers". The claimed compositions, comprising lamellar vesicles having, at most 10% block copolymers, can not be said to be "formed from" the copolymers.

Martin

The rejection of the claims over Martin is also traversed. Martin teaches liposomes formed from lipids. The liposomes have block copolymers attached thereto. The membranes are not "formed from amphiphilic copolymers", as recited in the present claims. Again, Applicants do not need to limit the present claims to recite that they do not exclude liposomes and other material from contributing to the membrane, as suggested by the Examiner.

103 Rejection

Wooley alone or combined with Martin

As clearly shown by the evidence submitted by Applicant in the previous response, Wooley does not teach or suggest hollow vesicles- i.e. vesicles having a shell enclosing an interior void. Wooley teaches microparticles formed from amphiphilic copolymers, having a crosslinked shell and an interior core domain. The hydrophilic portion of the amphiphilic copolymer forms the shell domain and the hydrophobic portion forms the interior core domain, or vice versa.

Martin does not teach stabilizing vesicles to form nanocapsules. Wooley does not teach hollow vesicles. Accordingly, these references, taken alone or in combination, do not render the claimed invention obvious. This rejection is traversed.

The Examiner's reasoning on page 7 does not negate Applicant's argument:

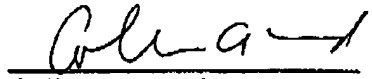
> "Based on this, one can interpret that what is discussed in exhibits D and E is the achievement by the inventors of WO to make the center core totally empty as a cage structure whereas the particles in WO are only partially empty if they are not cross-linked."

This is exactly what Applicant's argued is shown by exhibits D and E- the achievement by the inventors of Wooley (WO) of hollow vesicles ("empty as a cage structure"). The vesicles disclosed in WO were not hollow. Thus WO does not teach or render obvious the claimed invention.

CONCLUSION

None of the references that were cited teach or suggest hollow vesicles or nanocapsules formed from triblock amphiphilic copolymers. None of the references teach or suggest nanocapsules formed by end group crosslinking vesicles formed from amphiphilic copolymers. Accordingly, it is respectfully submitted that the references are not appropriate as the basis of rejection of the claims.

Respectfully submitted,



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Response to Office Action

Listing of Claims

1. (previously presented) Hollow vesicles comprising membranes formed from amphiphilic copolymers having hydrophobic and hydrophilic segments, wherein the copolymers are ABA copolymers, and wherein one of A and B is hydrophobic and the other is hydrophilic.

2. cancelled

3. (previously presented) Hollow nanocapsules formed by stabilization of the vesicles of claim 1.

4. (previously presented) Hollow nanocapsules formed by stabilization of vesicles comprising membranes formed from amphiphilic copolymers having hydrophobic and hydrophilic segments, wherein the vesicles are stabilized by end group polymerization of the copolymers.

5. (previously presented) The nanocapsules of claim 3, wherein the vesicles are stabilized via crosslinking of the copolymers.

6. (previously presented) The nanocapsules of claim 4, wherein the copolymers are AB copolymers, wherein one of A and B is hydrophobic and the other is hydrophilic.

7. cancelled

8. cancelled

9. (previously presented) The nanocapsules of claim 4, wherein an active agent is encapsulated within the nanocapsule.

10. (original) The vesicles of claim 1, wherein an active agent is encapsulated within the vesicle.

11. (previously presented) The nanocapsules of claim 3, wherein an active agent is encapsulated within the nanocapsule.

12. (previously presented) The vesicles of claim 1, wherein the vesicles comprise a hydrophilic inner layer, a hydrophobic middle layer and a hydrophilic outer layer.

13. (previously presented) The vesicles of claim 1, wherein the vesicles comprise a hydrophobic inner layer, a hydrophilic middle layer and a hydrophobic outer layer.

14. (previously presented) The vesicles of claim 1, wherein the copolymers are U-shaped and the vesicles have a hydrophobic inner layer and a hydrophilic outer layer, or a hydrophilic inner layer and a hydrophobic outer layer.

15. cancelled

16. (original) The nanocapsules of claim 4, wherein the polymerization is via photopolymerization.

17. (previously presented) The vesicles of claim 1, wherein one or more molecules are incorporated into the vesicle membrane.

18. (original) The nanocapsules of claim 3, wherein the hollow morphology of the nanocapsules is preserved when the nanocapsules are dry.

19. (original) The vesicles of claim 1, wherein the vesicles are biodegradable.

20. (original) The nanocapsules of claim 3, wherein the nanocapsules are biodegradable.

21. - 26. cancelled

27. (original) The vesicles of claim 1 further comprising targeting molecules bound to the surface of the vesicles.

28. (original) The vesicles of claim 27 wherein the targeting molecules are selected from the group consisting of carbohydrates, proteins, folic acid, peptides, peptoids, and antibodies.

29. (previously presented) The nanocapsules of claim 4, wherein the hollow morphology of the nanocapsules is preserved when the nanocapsules are dry.

30. (previously presented) The nanocapsules of claim 4, wherein the nanocapsules are biodegradable.